K121434

SIEMENS *September 28, 2012*

510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR § 807.92.

General Information

NOV 5 2012

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Device Name Software *syngo* MR D13A for the MAGNETOM systems Aera/Skyra/Avanto/Verio

CFR Code 21 CFR § 892.1000

Classification Class II

Product Codes LNH, LNI, MOS

Classification Name Magnetic Resonance Diagnostic Device, MR Spectroscopy, MR Coils

Information Supporting Substantial Equivalence

DEVICE DESCRIPTION

The software *syngo* MR D13A is the latest software version for four Siemens MR scanners: MAGNETOM Aera (1.5T), Skyra (3T), Avanto (1.5T), and Verio (3T). New scanners will be manufactured with this software version; existing scanners can be upgraded to this software version. The new software version includes new software sequences, applications, coils and other hardware for the four MAGNETOM scanners. While some new features (hardware and software) are only available for certain scanners (of the four listed), the basic *syngo* MR D13A software will run on each of the four MAGNETOM systems.

Summary of New Features with *syngo* MR D13A:

Software

- New sequences for all four systems for body, neurological, abdominal, orthopedic, and cardiac imaging, and for spectroscopy
- New or modified applications/software for all four systems:
  - Dot Engine improvements
  - Image processing and visualization improvements
  - Mapping improvements
  - Improved iPAT
  - Networked Scanner improvements
- Dot Engines now available for MAGNETOM Avanto & Verio (previously for Aera & Skyra with software *syngo* MR D11)
- New Dot Engines for MAGNETOM Aera & Skyra
- Multi Nuclear Option now available for MAGNETOM Skyra (previously for Avanto & Verio with software *syngo* MR B17)

Hardware

- New coils for Aera & Skyra only:
  - TxRx CP Head Coil
  - TxRx 15ch Knee Coil
  - 4 Channel Special Purpose Coil
- New coils for Avanto & Verio only:
  - Sentinelle Vanguard Breast 16ch Coil
  - Sentinelle Endo Array coil
- Modified Magnet, Skyra only

INTENDED USE

The MAGNETOM systems Aera/Skyra/Avanto/Verio with software *syngo* MR D13A are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

The MAGNETOM systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

NONCLINICAL TESTS

The following performance testing was conducted on the subject device:

- The coils were tested for SNR, image uniformity, and heating.
- The magnet was tested for SNR, geometric distortion, image uniformity and slice profile/thickness/spacing.
- Dedicated phantom testing was conducted on the MP2RAGE sequence.
- The performance parameters of MNO Spectroscopy were phantom-tested.
- *syngo* ASL 3D was tested using a dedicated phantom.
- MR Elastography was tested using a dedicated phantom.
- T1 mapping with B1 correction was phantom-tested.
- All software features were verified and validated.

The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate devices to which it has been compared.

CLINICAL TESTS

There were not any clinical tests conducted to support the subject device and the substantial equivalence argument, however clinical images were provided to support the new coils as well as the new and modified software features of the subject device.

SUBSTANTIAL EQUIVALENCE

Software *syngo* MR D13A for the MAGNETOM systems Aera/Skyra/Avanto/Verio is substantially equivalent to the following predicate devices:

	Predicate Device Name	Manufacturer	510(k) Number	FDA Clearance Date
1	MAGNETOM Aera & MAGNETOM Skyra with *syngo*® MR D11	Siemens Medical Solutions	K111242	November 23, 2011
2	MAGNETOM Avanto & MAGNETOM Verio with *syngo*® MR B17	Siemens Medical Solutions	K082427	November 7, 2008
3	MR-Touch	GE Medical Systems LLC	K083421	July 24, 2009
4	3D ASL	GE Medical Systems LLC.	K092925	January 6, 2010
5	TxRx 1.5T & 3T 15ch Knee Coils	Quality Electrodynamics (QED)	K082636	September 25, 2008
6	TxRx 1.5T & 3T CP Head Coils	Quality Electrodynamics (QED)	K091114	May 1, 2009
7	Sentinelle Endo Coil	Sentinelle Medical Inc	K103274	August 18, 2011
8	Sentinelle 16ch Breast Coil	Sentinelle Medical Inc	K112112	August 25, 2011

SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

The MAGNETOM systems Aera/Skyra/Avanto/Verio with software *syngo* MR D13A conform to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

SUBSTANTIAL EQUIVALENCE CONCLUSION

There are no changes to the Indications for Use for the subject device, compared to that of the predicate MAGNETOM scanners with software *syngo* MR D11 and *syngo* MR B17. The differences between the subject device and the predicate

devices, which include the aforementioned new sequences, applications, coils, and hardware, give the systems greater capabilities than the predicate devices, but have the same technological characteristics as the predicate devices, are similar to the functionalities of the predicate devices, and do not introduce any new issues of safety or effectiveness.

Therefore, Siemens believes that the subject device, software version *syngo* MR D13A for MAGNETOM systems Aera, Skyra, Avanto, and Verio, is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Re: K121434
Trade/Device Name: Software syngo MR D13A for the MAGNETOM systems Aera/Skyra/Avanto/Verio
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, and MOS
Dated: October 10, 2012
Received: October 11, 2012

Dear Ms. Byrne:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known) _____

Device Names: **Software *syngo* MR D13A for the MAGNETOM systems Aera/Skyra/Avanto/Verio**

Indications for Use

The MAGNETOM systems described above are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OVID)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121434